ISRCTN12604075 https://doi.org/10.1186/ISRCTN12604075

Safety trial of a locally-developed trunk and lower limb rehabilitation robot

Submission date
17/01/2025

Recruitment status
No longer recruiting

Registration date
24/01/2025

Overall study status
Completed

Last Edited
23/01/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The TAYO project aims to improve physical therapy care using a device called the Lower Limb Mobilization (LLMo). This device helps physical therapists perform passive range of motion exercises for people in the early stages of recovery after a stroke.

Who can participate?
Healthy individuals aged 18 to 65 years old.

What does the study involve?
Participants will perform range of motion exercises using the LLMo device. During the trial, their vital signs, comfort, and pain levels will be continuously monitored to ensure the device's safety.

What are the possible benefits and risks of participating?
Participants may feel some stretching in their lower extremities. Although the device is external and does not exchange energy with the patient, there is a risk associated with the device moving the participants' limbs. The device has passed rigorous mechanical and electrical tests to ensure safety.

Where is the study run from?
The study is conducted at the De La Salle University - Laguna Campus research lab (Philippines)

When is the study starting and how long is it expected to run for?
March 2023 to June 2023

Who is funding the study?
The study is funded by the Department of Science and Technology - Philippine Council for Health Research and Development (DOST-PCHRD)

Who is the main contact?
Engr. Julius Banayo, julius.banayo@dlsu.edu.ph

Contact information

Type(s)
Principal Investigator

Contact name
Dr Armyn Sy

ORCID ID
http://orcid.org/0009-0005-4838-2735

Contact details
2401 Taft Ave.
Manila
Philippines
922
+63 9177748816
armyn.sy@dlsu.edu.ph

Type(s)
Public, Scientific

Contact name
Mr Julius Banayo

Contact details
727V+352, LTI Spine Road, Laguna Blvd
Biñan, Laguna
Philippines
4024
+63 9162870211
julius.banayo@dlsu.edu.ph

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AHMC 2023-01

Study information

Scientific Title
A pilot study among normal subjects on the safety and functionality of a locally-developed trunk and lower limb rehabilitation robot

Study objectives
The lower limb rehabilitation robot is safe to use among healthy participants

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2023, Asian Hospital and Medical Center Research Ethics Committee (2205 Civic Dr, Muntinlupa, Metro Manila, 1780, Philippines; +63 (02) 8771 9000; info@asianhospital.com), ref: AHMC 2023-01

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Safety

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Passive range of motion among healthy adult participants

Interventions
After meeting the inclusion criteria and medical evaluation, participants' vital signs (blood pressure, heart rate, and oxygen saturation) and lower limb measurements were recorded prior to the trial. They were then secured to the Lower Limb Mobilization (LLMo) device and performed three repetitions of each prescribed lower limb exercise. Lower limb angles were measured after each repetition. Throughout the exercises, the attending physiatrist and physiotherapist consistently monitored the participants, sought feedback and pain assessments from participants. Following the exercises, participants' vital signs were recorded before, during and at end of exercise. Additionally, they were given a survey to assess their perceptions of the LLMo's safety, feasibility, and acceptability while performing exercises.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase

Phase 0

Drug/device/biological/vaccine name(s)
Lower Limb Mobilization Device (LLMo Device)

Primary outcome measure
Safety evaluation:
1. Safety checklist used to inspect device before the trial
2. Pain assessment administered as needed during the exercises
3. Adverse events reported as needed throughout the entire trials

Secondary outcome measures
1. Range of Motion of each exercise measured using goniometer at the end of each movement
2. Range of Motion of each exercise measured using device software at the end of each movement
3. Patient perception of safety, feasibility, and acceptability measured using a survey at the end of each session
4. Comments regarding comfort recorded verbally over the course of the whole exercise session; Physiatrist wrote down notes comments in participant chart

Overall study start date
23/03/2023

Completion date
17/06/2023

Eligibility

Key inclusion criteria
1. Be able to follow instructions
2. Be at least 5'4" (1.63 m) to 6'2" (1.87 m)
3. Weigh less than 200 kg
4. Have full use of their trunk and lower extremities
5. Agree to have medical clearance sponsored by the research prior to participation (validity: 1-2 weeks from appointed clinical study participation)
6. Be fully vaccinated against COVID-19 (2 completed doses, with or without boosters)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex

Both

Target number of participants
18

Total final enrolment
18

Key exclusion criteria
With any known disabilities or comorbidities

Date of first enrolment
01/05/2023

Date of final enrolment
26/05/2023

Locations

Countries of recruitment
Philippines

Study participating centre
De La Salle University - Laguna Campus
727V+352, LTI Spine Road, Laguna Blvd
Biñan, Laguna
Philippines
4024

Sponsor information

Organisation
DLSU - Evelyn D. Ang - Institute of Biomedical Engineering and Health Technology

Sponsor details
2401 Taft Ave.
Manila
Philippines
922
+632 8524-4611 Local 360
ibeht@dlsu.edu.ph

Sponsor type
Research organisation

Website
https://ibeht.com/home

Funder(s)

Funder type
Government

Funder Name
Department of Science and Technology, Republic of the Philippines

Alternative Name(s)
Department of Science and Technology, Philippines Department of Science and Technology, Department of Science and Technology, Philippines, Kagawaran ng Agham at Teknolohiya, DOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Philippines

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	10/02/2023	23/01/2025	No	No